DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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August 16, 2004

WARNING LETTER
CIN-04-22642

VIA FEDERAL EXPRESS

Mr. Jerry May
Owner/President
Extended Care Air Therapy Systems, Inc.
7165 Payne Road
Roseville, OH 43777

Dear Mr. May:

An inspection of your medical device manufacturing firm located in Roseville, OH conducted by our investigator on June 28 and 29, July 1 and 2, 2004, revealed that your firm manufactures safety net enclosures for A/C powered hospital beds, a Class II medical device. These products are medical devices as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deviations from the QSR include, but are not limited to, the following:

Management Controls

1. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained. [21 CFR 820.20] For example:

   - A quality policy has not been established, documented, and implemented. [21 CFR 820.20(a)]
   - A quality plan has not been established, documented, and implemented. [21 CFR 820.20(d)]

- Quality system procedures have not been established. [21 CFR 820.20(e)] For example, there are no procedures for controlling production, for conducting quality audits and for controlling the design process.

2. Failure to conduct quality audits to assure that the quality system is in compliance the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR 820.22]

Production and Process Controls

3. Failure to provide documented instructions, standard operating procedures and methods that define and control the production processes of the ECAT'S 1000 safety net enclosure devices [21 CFR 820.70(a)].

4. Failure to perform acceptance activities, including inspections, tests, and other verification activities, for incoming components and in-process product; and failure to establish procedures for receiving, in-process and finished device acceptance. [21 CFR 820.80]

5. Failure to establish a Device Master Record for the ECAT'S 1000 safety net enclosure devices. [21 CFR 820.181]

6. Failure to establish procedures to ensure that the device history records for each batch, lot or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System Regulation. [21 CFR 820.184] Specifically, there are no device history records for the safety enclosure devices that have been distributed from 1998 to the present.

7. Failure to establish and maintain procedures for addressing the identification, documentation, evaluation, segregation, disposition, and investigation of nonconforming products; and failure to document any nonconformances. [21 CFR 820.90(a)]

Corrective and Preventive Actions

8. Failure to establish and maintain procedures for implementing corrective and preventive actions; and failure to document corrective and preventive activities, including analysis of quality data sources, investigations of causes of nonconformances, and implementation of corrective and preventive actions. [21 CFR 820.100]

9. Failure to formally designate a unit for handling complaints; and failure to establish complaint handling procedures for receiving, reviewing, and evaluating complaints; and failure to document the investigations and corrective actions taken. [21 CFR 820.198(a) and (e)].

Design Controls

10. Failure to establish procedures to control the design process for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation [21 CFR 820.30(i)]. Specifically, no design controls were used to develop the ECAT'S 1000 safety net enclosure device.

Medical Device Reporting

11. Failure to develop, maintain, and implement written Medical Device Reporting procedures. [21 CFR 803.17]

You should know that these are serious violations of the law. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, it is your responsibility to assure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We have received your letter dated July 9, 2004 in response to the FDA-483 stating that you will correct all deficiencies. Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these deficiencies. In addition, please submit any additional documentation to show the corrections initiated

in conformance with the requirements of the Quality System Regulation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your written response to this Warning Letter should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, extension 167, or you may forward a facsimile to her at (513) 679-2775.

Sincerely,

Deborah Greile
for Carol A. Heppe
District Director
Cincinnati District